

FOOD AND DRUG ADMINISTRATION

Center for Drug Evaluation and Research Oncologic Drugs Advisory Committee AGENDA

May 5, 2005:

The committee will discuss New Drug Application (NDA) 21-824, Zarnestra® (tipifarnib) Film Coated Tablets, Tibotec Therapeutics, a division of Ortho Biotech, LP, proposed indication for the treatment of elderly patients with newly diagnosed poor-risk acute myeloid leukemia (AML).

8:30 a.m.	Call to Order	Silvana Martino, D.O. Chair, ODAC
	Introduction of Committee	
	Conflict of Interest Statement	Johanna Clifford, M.S., RN Executive Secretary, ODAC
8:45 a.m.	Opening Remarks	Richard Pazdur, M.D., Director Division of Oncology Drug Products, FDA
9:00 a.m.	<u>Sponsor Presentation</u>	Tibotec Therapeutics, Inc.
	Introduction	Robert DeLap, M.D., Ph.D. Vice President, Regulatory Affairs
	Elderly	Richard Stone, M.D. Clinical Director, Department of Adult Oncology Dana Farber Cancer Institute & Associate Professor Harvard Medical School
	Clinical Data	Alain Thibault, M.D. Senior Director Oncology Clinical Research
	Benefit/Risk	Alex Zukiwski, M.D. Vice President Oncology Clinical Research
10:00 a.m.	<u>FDA Presentation</u>	
	NDA 21-824, Zarnestra	Qin Ryan, M.D. Medical Officer, Division of Oncology Drug Products, FDA

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Agenda Continued:

10:45 a.m. AML in Older Individuals

Frederick R. Appelbaum, M.D.
Director, Clinical Research Division
Fred Hutchinson Cancer Research Center
Seattle, Washington

11:00 a.m. Open Public Hearing

12:00 p.m. Lunch

1:00 p.m. *Questions from the Committee*

1:45 p.m. Break

2:00 p.m. Discussion of the Questions

4:30 p.m. Adjourn